SAFE SEPTAL NEEDLE AND METHOD FOR ITS USE

FIELD OF THE INVENTION

The present invention is directed to an apparatus and method for introducing an electrophysiology catheter into the left atrium of the heart through the atrial septum and more particularly to an apparatus and method for forming an opening in the atrial septum while minimizing risk of damage to the superior left atrium wall.

BACKGROUND OF THE INVENTION

Electrophysiology catheters are commonly used for mapping electrical activity in a heart. Electrophysiology is a specialty within the field of cardiology for diagnosis and treatment of electrical abnormalities of the heart. By mapping the electrical activity in the heart, ectopic sites of electrical activation or other electrical activation pathways that contribute to heart malfunctions may be detected. This type of information may then allow a cardiologist to intervene and destroy the malfunctioning heart tissues.

Occasionally, an electrical abnormality occurs in a location that is difficult to reach with standard catheter capabilities. The left atrium of the heart is one such location. When an electrical abnormality occurs in the left atrium, a dilation catheter, or dilator, is typically inserted percutaneously, passed through one or more major blood vessels, and inserted into a right atrium of the heart and then passed trans-septally into the left atrium. Specifically, a needle is passed through the dilator and inserted into and through the atrial septum to puncture the atrial septum to allow access to the left atrium for a therapeutic catheter. [Is dilator removed and a therapeutic catheter inserted? How does it find the hold?]

A current technique for puncturing the atrial septum includes positioning a dilator adjacent to an area of the atrial septum that is desired to be punctured

(typically at the fossa ovalis), inserting a needle into the dilator, feeding the needle through the dilator until the needle protrudes beyond the dilator, and puncturing the atrial septum with the needle. This technique has several disadvantages. For example, locating the desired puncture site and then inserting and feeding a separate needle into the dilator increases the procedure time, and increases the likelihood that the dilator will be inadvertently moved before the needle reaches the desired puncture site, thus requiring a repositioning of the dilator. If the repositioning is performed with the needle inside the dilator, the possibility exists for the needle to slide out of the dilator and damage venous or atrial structures. If the needle is removed during repositioning, procedure time is again extended during reinsertion and re-feeding of the needle into the dilator, and the risk of an inadvertent movement of the dilator during reinsertion and re-feeding of the needle again exists.

Another more serious disadvantage of the current technique is that, to dilate the hole created by the needle puncture sufficiently for a guiding sheath to fit through with the dilator, the sharp needle must be advanced ten to twenty millimeters into the left atrium, which is difficult to control. This advancement brings the sharp edge of the needle dangerously close to the superior wall of the left atrium, and might result in perforation, especially if the left atrium is small. Moreover, a force in an axial direction is required to insert the needle into and through the atrial septum, yet there is no means for controlling the maximum protrusion of the needle from the dilator. As a result, a tendency exists for the operator to continue to apply a forward force to the needle even after the needle has crossed the atrial septum. This risks damage to atrial structures in the left atria or even cardiac puncture if the needle protrudes too far from the dilator.

SUMMARY OF THE INVENTION

The present invention addresses the above-referenced problems by providing a method for puncturing a first, proximal membrane without puncturing a second, distal membrane. This method can be used to puncture the atrial septum without risk of puncturing the lateral left atrial wall. The method comprises providing a device comprising an elongated tubular member and an elongated body slidably disposed within the elongated tubular member. The elongated body has a distal region at least a portion of which is made of a shape-memory material in a preformed curved configuration. The elongated body is movable from a first retracted position completely disposed within the elongated tubular member, which requires the distal tip region of the elongated body to be in a generally straight configuration, to a second extended position where the distal tip region has been advanced out of the distal end of the tubular member. In this extended position, the distal region of the elongated body reverts to its preformed curved configuration.

In the method, the tubular member is advanced in the traditional manner into the right atrium to a position adjacent to a atrial septum. The elongated body is then advanced distally from its first retracted position toward its second extended position. In so doing, the distal end of the elongated body, which has a distal tip portion sufficiently rigid and sharp to puncture the first proximal membrane, e.g., the atrial septum, punctures the first, proximal membrane, e.g., the atrial septum. As the elongated body is further advanced through the punctured proximal membrane, the distal tip of the elongated body deflects into its preformed curved configuration. In the curved configuration, the distal tip of the elongated body is generally hook or j-shaped, creating a "blunt" distal surface that faces the second, distal membrane, e.g., the lateral left atrial wall. As used herein, "blunt" refers to any surface, e.g., a curved surface, that will not puncture

the second distal membrane.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1a is a side view of the first and second embodiments of the invention in a generally straight configuration;

FIG. 1b is a side view of the embodiments of FIG. 1a in a curved configuration;

FIG. 1c is a side, cross-sectional view of a preferred joint formed between a solid proximal region and a solid distal region of an elongated body as shown in FIG. 1a.

FIG 1d is a side, cross-sectional view of a preferred joint formed between a tubular proximal region and a tubular distal region of an elongated body as shown in FIG 1b.

FIG. 2a is a side view of a generally straight configuration of an elongated tube with a box cut slotted transformative region of the distal region;

FIG. 2b is a magnified side view of a curved configuration of the distal region of the elongated tube depicted in FIG. 2a;

FIG. 3a is a magnified side view of a generally straight configuration of a key hole cut slotted transformative region of the distal region of an elongated tube;

FIG. 3b is a magnified side view of a curved configuration of the distal region of the elongated tube depicted in FIG. 3a;

FIG. 3c is a perspective view of the transformative region of the embodiment of FIG. 3a.

FIG. 3d is a cut away view of the transformative region of the embodiment

of FIG. 3a.

FIG. 4a is a side view of another embodiment of the invention in a generally straight configuration in which a portion of the transformative region has been removed;

FIG. 4b is a side view of the embodiment of FIG. 4a in a curved configuration;

FIG. 5a is a magnified side view of a generally straight configuration of a spiral cut slotted transformative region of the distal region of an elongated tube in which the slots are angled, i.e., not perpendicular to the axis of the transformative region;

FIG. 5b is a magnified side view of a curved configuration of the distal region of the elongated tube depicted in FIG. 5a;

FIG. 6 is a schematic depicting the first configuration of a distal tip of a elongated body according to the invention;

FIG. 7 is a schematic depicting the second configuration of a distal tip of an elongated body according to the invention;

FIG. 8a is a schematic depicting a generally straight configuration of a penetrator mounted on a compression region contained within an elongated tubular member according to an alternative embodiment of the invention;

FIG. 8b is a schematic depicting a generally compressed configuration of the penetrator and compression region depicted in FIG. 8a.

DETAILED DESCRIPTION OF THE INVENTION

The invention provides a method for puncturing a proximal membrane, e.g., the atrial septum, without puncturing a distal membrane, e.g., the superior left atrium wall. With reference to **FIGs. 6 and 7**, the method comprises providing a device comprising an elongated body **10** slidably disposed within an elongated tubular member **12**. The elongated tubular member **12** may comprise

a standard guiding sheath, or a standard vessel dilator. An example of a suitable guiding sheath for use with this invention is the Preface™ Braided Guiding Sheath, commercially available from Biosense Webster (Diamond Bar, California). An example of a suitable dilator for use with this invention is the vessel dilator provided with the Preface™ Braided Guiding Sheath. The elongated tubular member **12** may comprise any suitable material, as is known in the art. Preferably, the elongated tubular member **12** comprises a polymeric construction. The outer diameter of the elongated tubular member **12** preferably ranges from about 6 french to about 12 french. The inner diameter of the elongated tubular member **12** preferably ranges from about 0.018 inch to about 0.040 inch. The distal tip of the elongated tubular member **12** may have an inner diameter ranging from about 0.01 inch to about 0.04 inch. Preferably, the inner diameter at the distal tip ranges from about 0.015 inch to about 0.040 inch.

With reference to **FIGs 1a and 1b**, the elongated body **10**, comprises a distal region **26**, and a proximal region **28**. The distal region **26** includes a distal tip portion **16** and a transformative region **30**. The distal tip portion **16** of the distal region **26** preferably has a beveled distal end to provide a sharp puncturing tip.

The proximal region **28** comprises an elongated wire or tube made of any suitable material, as is known in the art. Preferably, the proximal region **28** of the elongated body **10** comprises stainless steel or polyamide. The proximal region **28** may comprise a diameter ranging from 0.01 to 0.04 inches. Preferably, the proximal region **28** of the elongated body **10** comprises an outer diameter ranging from 0.015 to 0.035 inches. The distal-most end of the proximal region **28** of the elongated body **10** preferably comprises a circumferential bevel or taper to provide a generally smooth transition between the proximal region and the distal region. The angle of the taper may vary as desired, but should be uniform.

In this embodiment, the distal region **26** of the elongated body **10** may be

solid or tubular. At least the transformative region **30**, and preferably the entire distal region **26,** is made of a shape-memory material. As used herein "shape-memory" refers to the property of certain materials that allows the material to return to its preformed shape after being bent as a result of an applied force. Any suitable shape-memory material may be used. Preferably, the distal region **26** of the body **10** is made of nitinol or shape memory polymer. The distal region **26** of the elongated body **10**, if solid, preferably has a diameter ranging from about 0.010 inch to about 0.035 inch, and more preferably about 0.015 inch. If tubular, the outer diameter ranges from about 0.010 inch to about 0.035 inch, and the inner diameter ranges from about 0.007 inch to about 0.032 inch. More preferably, the outer diameter is about 0.015 inch and the inner diameter is about 0.012 inch:

The distal tip portion **16** of the elongated wire or tube **10** is of sufficient length to puncture completely through the proximal membrane **15**, e.g., the atrial septum. In a preferred embodiment, the length of the distal tip **16** ranges from about 0.10 inch to about 0.30 inch. Preferably, the length of the distal tip portion **16** ranges from 0.120 to 0.170 inches.

The proximal region **28** and the distal region **26** of the elongated body **10** may all comprise a single unitary structure or may be separate structures which are joined. If a single connecting wire or tube is used, it should have shape-memory capability. If the proximal and distal regions **28** and **26** are separate structures, they may be joined by way of suitable means. For example, as shown in **FIGs. 1c and 1d**, the proximal region **28** may have an axial recess – at its distal end which recesses the proximal end of the wire or tube that forms the distal region **26**. This joint may be secured by welding, adhesive, or any other suitable means.

The distal region **26** of the elongated body **10** includes a transformative region **30**, located immediately proximal to the distal tip portion **16** of the

elongated body **10** that is preformed into a curved configuration. When the transformative region **30** is confined within the elongated tubular member **12**, with the distal end of the distal tip portion **16** outside the distal end **14** of the elongated tubular member **12**, the transformative region **30** is maintained in a generally straight configuration. The distal tip portion **16**, which is generally rigid and sharp punctures the proximal membrane **15** upon distal advancement out of the tubular member **12** against the proximal membrane **15**. As the transformative region **30** is advanced distally out of the distal end **14** of the elongated tubular member **12** to its extended position, it returns to its preformed, e.g., curved shape, as shown in **FIG. 7**, thus providing a curved or blunt distal surface **18** facing the distal membrane **20**.

In a preferred embodiment, the distal region **26** has a length ranging from about 0.1 inch to about 0.3 inch. More preferably, the length of the distal region **26** ranges from about 0.165 inch to about 0.255 inch. The preferred range allows the distal tip portion **16**, in a sufficiently straight configuration, to penetrate the first membrane and thereafter bend in a sufficiently small radius to ensure that the tip turns prior to engaging the second membrane. The transformative region **30** may be curved at any radius suitable to create a blunt distal surface **18** facing the distal membrane **20**. When the elongated body **10** comprises an elongated tube, it may be used to deliver fluid, such as contrast media, saline and/or drugs to the region of the punctured proximal membrane **15**, as discussed further below.

In other embodiments, depicted in **FIGs. 2a, 2b, 3a, 3b, 3c, 3d, 5a, and 5b**, the elongated body **10** comprises an elongated tube having a "slotted" transformative region **30** and a rigid, non-slotted, distal tip portion **16** of sufficient length to puncture entirely through the proximal membrane **15**. At least the slotted transformative region **30** and preferably the entire distal region **26** is made of a shape-memory material, e.g., nitinol. The transformative region

30 comprises a plurality of slots or shaped cuts (collectively referred to herein as "slots") to promote flexibility and to enable a tighter bending radius, to thereby provide a curved, non-puncturing surface **18** facing the distal membrane **20** once the proximal membrane has been punctured. In such embodiments, the transformative region **30**, which is preformed into a curved configuration will regain that precurved configuration upon advancement out of the tubular member **12** and through the punctured proximal membrane **15**.

The slotted transformative region **30** also serves to control the direction and extent of bending of the distal end **26** of the elongated tube **10**. That is, the slotted transformative region **30** may include one or more partial circumferential slots **32** extending through the outer wall of the elongated tube which affect the direction in which and the extent to which the transformative region **30** can bend. The slots **32** of the slotted transformative region **30** may be arranged to permit the distal region **26** of the elongated tube **10** to bend in only one direction, as shown. In such an arrangement, the slots **32** may be aligned along the axis of the slotted transformative region **30**. Alternatively, the slots **32** of the slotted transformative region **30** may be arranged such that the distal region **26** of the elongated tube **10** bends in more than one plane, e.g., the slots are not axially aligned.

With particular reference to **FIGS. 3a-d**, the outer wall of the slotted transformative region **30** can be viewed as having a first, preferably compressible, side **34** and a second, preferably expandable, side **36** opposite the first side. The first side **34** is the side forming the inner radius of the curve formed by the transformative region **30** once extended out of the tubular member **12**. The second side **36** is the side forming the outer radius of the curved transformative region **30**.

The slotted transformative region **30** includes a plurality of slots **32** that extend from the second side **36** toward the first side **34** and/or a plurality of slots

that extend from the first side **34** toward the second side **36**. The number, size, geometry and location of the slots may vary as desired. Preferably the slots are uniformly spaced, but the spacing may vary as desired in order to achieve the desired geometry.

In the embodiment shown in **FIG. 2a**, each slot **32** may be generally perpendicular to the long axis of the transformative region **30**. Alternatively, as depicted in **FIG. 5a**, the slots **32** could be angled relative to the axis of the transformative region **30**, so long as the slots **32** are generally transverse to the long axis of the transformative region **30**.

In the embodiment shown in **FIGs. 3a-d**, both the first side **34** and the second side **36** include a plurality of slots **32**. The slots extending from the first side **34** toward the second side **36** are preferably aligned with the slots extending from the second side **36** toward the first side **34** as shown. Also , as shown, the width of the slots extending from the first side **34** toward the second side is sufficient to allow the transformative region to bend to the desired curvature.

In this arrangement, when the transformative region returns to its preformed curved configuration, the walls of the slots in the first side **34** compress toward each other and the walls of the slots in the second side **36** expand away from each other as shown in **Fig. 3b**. The number, placement, size and shape of the slots can vary depending on the desired effect. Preferably, the total number of slots in the slotted transformative region **30** ranges from about 30 to about 200, and the center of the slots are spaced apart by a distance of from about 0.008 inch to about 0.180 inch, preferably about 0.060 inch.

The "depth" of the slots **32**, i.e., the circumferential arc in the wall of the tubular shaft of the tip region **26** made by the slots may also vary. In the embodiment shown in **FIGs. 3a and 3b**, the circumferential arc of the slots **32** does not extend past the longitudinal midline of the transformative region **30**. In other embodiments where the slots in the first side **34** are not aligned with the

expandable slots in the second side, the slots may, if desired, extend past the longitudinal midline of the transformative region. The arcs of the compressible slots may vary from each other and may vary from those of any expandable slots.

The shapes and placement of the slots can affect the extent to which, and the direction in which, the slotted transformative region **30** will bend. In the embodiment depicted in **FIGs. 3a-d,** the slots are generally "key-hole" shaped when viewed from the side. Specifically, each compressible slot comprises a rectangular or preferably slightly tapered or trapezoidal region **38** that terminates in a general circular region **40.** Thus, the compressible slots of this embodiment, as well as that of **FIGS. 4 and 5**, involve the removal of material from the transformative region **30**.

In the embodiment of **FIGs. 3a-3d**, each expandable slot comprises a cut **42** generally perpendicular to the axis of the transformative region **30**. The cuts **42** terminate in generally circular regions **44** like the circular regions **40** of the compressible slots. The circular regions **44** of the expandable slots can have the same size as those of the compressible slots or may differ as desired. It is understood that the walls formed by cuts **42** may be spaced apart if desired.

In another embodiment, the elongated body **10** comprises an elongated tube, as described above, wherein a substantial portion of the transformative region **30** of the elongated body **10** is completely removed, as depicted in **FIGs. 4a and 4b**. Removal of a substantial portion of the transformative region **30** helps promote flexibility of that region enabling a tighter bending radius and reducing strain on the tubing which increases the ability of the assembly to withstand fatigue. The transformative region **30** may be pre-curved in any radius suitable to present a non-puncturing surface **18** toward the distal membrane **20**. Preferably, the transformative region **30** has a preformed curvature from about 120° to about 270°, preferably 180°, and has a radius of about 0.160 inch to about 0.300 inch, preferably about 0.250 inch.

In any of the embodiments where a portion of the transformative region **30** is removed, a polymeric covering **31** may optionally be coated onto the transformative region **30** to cover any sharp edges. If desired, the polymeric coating **31** may be coated over the entire length of the elongated body **10**. The polymeric covering **31** may comprise any suitable material, as is known in the art, e.g., nylon, polyurethane, fiberglass reinforced plastic, or polyester. Preferably, the polymeric covering **31** comprises a highly flexible segment that acts as a fluid conduit to the distal tip portion **16**. For example, the polymeric covering **31** may comprise a permeable or semi-permeable membrane for delivering fluids, such as contrast media, saline or drugs.

In those embodiments having a slotted transformative region **30** when the elongated body **10** is advanced distally such that the distal region **26** extends out of the tubular member **12**, the slotted transformative region **30** will bend in a direction toward the compressible side **34** and return to its preformed curved configuration. Each of the above-described arrangements of the slots **32** enables the transformative region **30** to bend generally within a single desired plane, assuring that the distal region **26** bends in a manner to carry the sharp distal tip portion **16** away from the second or distal membrane.

In an alternative embodiment, depicted in **FIGs. 8a and b**, the elongated body **10** comprises a penetrator **50** mounted on a compression region **52**. The penetrator is sufficiently long to puncture entirely through the proximal membrane **15**, and comprises any suitable, generally non-compressible material. The compression region **52** may either comprise a very flexible tubular material, e.g., a flexible polymer, or a plurality of strips of a flexible material attaching the penetrator to the elongated body **10**.

In these embodiments, the compression region **52** remains in a generally straight and rigid configuration while contained within the elongated tubular member **12**, as shown in **FIG. 8a**. While the compression region **52** is so

contained, the penetrator **50** punctures completely through the proximal membrane **15**. Upon advancement out of the elongated tubular member **12**, the compression region **52** compress and/or flexes, e.g. bows outwardly, upon terminating the advancement of the penetrator, as shown in **FIG. 8b**. The compression of the compression region **52** prevents the penetrator from puncturing a second membrane by eliminating the support behind the penetrator that is needed to force the penetrator through the membrane. Any material may be used for the compression region **52** that is sufficiently flexible such that the compression region **52**, when advanced out of the elongated tubular member **12**, will compress upon contact of the penetrator with a second membrane.

Each embodiment of the present invention may further comprise a handle shaped to allow precise manipulation of the elongated body **10** and the elongated tubular member **12**. The handle controls the direction of curvature of the elongated body **10**, as well as both the advancement of the elongated body **10** and the advancement of the elongated tubular member **12**. Also, the handle facilitates the separate advancement of the elongated body **10** relative to the advancement of the elongated tubular member **12**.

The handle may also optionally include either a pressure transducer or a connection to a pressure transducer for monitoring the pressure surrounding the elongated body**10**. In those embodiments where the elongated body **10** comprises an elongated tube, the handle may also include a standard luer lock connection to facilitate infusion of fluids through the elongated tubular body **10**. Nonlimiting examples of handles suitable for use with the present invention include those disclosed in U.S. Patent Nos. 6,540,725, 6,575,931, 6,623,473 and 6,623,474, and U.S. Patent Application Nos. 10/118,679, 10/693,553, 10/694,118, 09/711,648, the entire disclosures of which are incorporated herein by reference.

Each embodiment of the present invention may be used to puncture the atrial septum of the heart, and thereby gain access to the left atrium of the

heart. In this trans-septal puncture procedure, the atrial septum is the proximal membrane **15** to be punctured, and the lateral left atrial wall is the distal membrane **20** not to be punctured. To puncture the atrial septum, the distal region of the elongated tubular body **10** is positioned against the atrial septum, typically at or near the fossa ovalis. The elongated body **10** is then distally advanced through the elongated tubular member **12** to the first configuration, depicted in **FIG. 6**, to its extended position outside the distal end **22** of the elongated tubular member **12**. The distal tip portion **16** of the elongated body **10** is sufficiently rigid and sharp to puncture the atrial septum. As the distal region **26** of the elongated body **10** is advanced through the elongated tubular member **12**, it returns to its preformed curved configuration, depicted in **FIG. 7**. In the curved configuration, the distal tip portion **16** of the elongated body **10** points away from the lateral left atrial wall, thereby preventing the puncture of the lateral left atrial wall.

The preceding description has been presented with references to presently preferred embodiments of the invention. Persons skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structures can be practiced without meaningfully departing from the principle, spirit and scope of this invention.

For example, where the elongated body **10** is an elongated tube, fluid, such as contrast media, saline or drugs such as anticoagulants, can be delivered across the atrial septum into the left atrium of the heart. Contrast media is useful for determining the position within the heart where the elongated tubular member and the elongated body are located. Drugs, such as anticoagulants, can be used to control the clotting of blood at the puncture site.

As another example, the elongated body **10** can have a pressure monitoring device, if desired, mounted on its proximal end. Such a pressure monitoring device can be used to determine the location of the elongated body **10**

within the heart due to the differences in pressure among the different chambers within the heart. For example, the pressure within the right atrium of the heart differs from that of the left atrium and from aortic pressure or pressure within a pulmonary artery. A pressure monitoring device will read the pressure at the location of the elongated body, and that reading will indicate whether the elongated body is located within the right atrium, the left atrium, a pulmonary artery or the aorta.

Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and shown in the accompanying drawings, but rather should be read as consistent with and as support for the following claims, which are to have their fullest and fairest scope.